

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**40257**

**CHEMISTRY REVIEW(S)**

DIVISION REVIEW SUMMARY

ANDA: 40-257

DRUG PRODUCT: Oxycodone Hydrochloride & Acetaminophen USP

FIRM: Mallinckrodt Chemical

DOSAGE FORM: Capsule

STRENGTH: 5 mg/500 mg

CONTAINER: 200 cc/100's and 950 cc/500's & 1,000's

CGMP STATEMENT/EIR UPDATE STATUS:

Acceptable dated 10/20/97.

BIO INFORMATION:

Acceptable dated 10/6/97.

VALIDATION

N/A

STABILITY

Lot number 9127V01521/ kg/ units was placed in accelerated stability studies. Based upon the acceptable stability data submitted, the proposed 24 months expiry is granted.

The container/closure systems are described in the container section of the application.

LABELING

Acceptable dated 7/8/98..

STERILIZATION VALIDATION

N/A

SIZE OF BIO/STABILITY BATCHES

Oxycodone HCL & APAP are manufactured by Mallinckrodt, DMFs respectively. These DMF were found acceptable on 3/3/1/98 and 6/2/98, respectively.

The stability batches are the same of the bio batches.

PROPOSED PRODUCTION BATCH

Blank batch record for the intended production batch size of kg or units is appended.

RECOMMENDATION:

Recommend approval of generic drug product Oxycodone  
HCl/Acetaminophen Capsules USP, 5 mg/500 mg.

SIGNATURE:

*Di.*  
**/S/**

DATE: May 26, 1998

*7/22/98*

1. CHEMISTRY REVIEW NO. 2
2. ANDA # 40-257
3. NAME AND ADDRESS OF APPLICANT  
Mallinckrodt Chemical Inc.  
16305 Swingley Ridge Drive  
Chesterfield, MO 63017
4. BASIS OF SUBMISSION  
There are no unexpired patents or exclusivities which are claimed by the RLD manufacturer for Tylox (Oxycodone and Acetaminophen Capsules, USP 5 mg/500 mg).
5. SUPPLEMENT(s)  
N/A
6. PROPRIETARY NAME
7. NONPROPRIETARY NAME  
Oxycodone HCL/Acetaminophen
8. SUPPLEMENT PROVIDE FOR:  
N/A
9. AMENDMENTS AND OTHER DATES:  
June 30, 1997- Original Submission  
October 6, 1997- Bio letter--waiver granted.  
January 21, 1998-- Deficiency letter  
March 12, 1998-- Amendment  
July 3, 1998-- Amendment
10. PHARMACOLOGICAL CATEGORY  
Pain reliever
11. Rx or OTC  
Rx
12. RELATED Drug Master Files  
--Mallinckrodt--Oxycodone HCl  
--Mallinckrodt--Acetaminophen
- - -
13. DOSAGE FORM  
Capsules
14. POTENCY  
5 mg/500 mg
15. CHEMICAL NAME AND STRUCTURE  
Oxy:4,5-alpha-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.  
APAP:4', hydroxy acetanilide

16. RECORDS AND REPORTS  
N/A

17. COMMENTS  
Responses to our deficiency letter dated 3/21/98 can be found **bolded** under each distinctive section of this review.

18. CONCLUSIONS AND RECOMMENDATIONS  
Recommend approval letter to issue.

19. REVIEWER: DATE COMPLETED:  
Edwin Ramos May 23, 1998

IS/ 5/20/98